DEPARTMENT OF VETERANS AFFAIRS Harry S. Truman Memorial Veterans' Hospital 800 Hospital Drive Columbia, Missouri

HPM 589A4-362 January 09, 2006 Issued by: Research

Research Misconduct

- 1. PURPOSE: To establish policy and procedures regarding potential Research Misconduct at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH).
- 2. DEFINITION: Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The expanded definitions as reported in Veterans Health Administration (VHA) Handbook 1058.2 dated May 4, 2005, are followed with regard to judgments pertaining to research misconduct.
- 3. POLICY: Research misconduct by research staff or other personnel associated with the Research Program at this facility is strictly prohibited. The HSTMVH is committed to conducting all research activities with integrity and with adherence to scientifically sound practices and ethical principles. In addition, the Research Program at this facility conforms to Federal Policy on Research Misconduct as codified at 65 Federal Register (Fed.Reg.) 76260 (December 6, 2000). All allegations of research misconduct will require appropriate reporting, inquiry and/or investigation, as required by VHA Handbooks 1058.1 and 1058.2.
- 4. SCOPE: Research misconduct policies and procedures apply to all Department of Veterans Affairs (VA) employees, including Without Compensation (WOC) staff, contractors, and Intergovernmental Personnel Agreement (IPA) personnel working within the Research Program at the HSTMVH. However, ethical lapses or other improprieties that do not fall within the definition of research misconduct are not covered by this Hospital Policy Memorandum (HPM). These other lapses or improprieties may include conflicts of interest, misallocation of funds, sexual harassment, discrimination, and breaches of human subjects protection or animal welfare requirements; such matters are subject to other VA regulations, policies, procedures, and, in some cases, laws.

5. RESPONSIBILITY:

- a. Hospital Director: The Hospital Director is the Institutional Official responsible for the Research and Development (R&D) Program, including oversight of research misconduct issues. The Hospital Director is responsible for designating a permanent Research Integrity Officer (RIO).
- b. Research Integrity Officer (RIO): The Hospital Director has designated the Associate Chief of Staff for Research and Development (ACOS/R&D) as the RIO at this facility. The RIO is responsible for:
 - (1) Receiving allegations of research misconduct
- (2) Coordinating and monitoring appropriate safeguards for respondents and informants

- (3) Keeping abreast of research misconduct policies, regulations, and laws
- (4) Informing hospital administrators, investigators, and research staff about research misconduct procedures
 - (5) Demonstrating objectivity and impartiality in executing RIO duties

6. PROCEDURES:

- a. Persons associated with the VA Research Program have responsibility to report suspicions or concerns about potential research misconduct, if they honestly believe credible evidence of misconduct exists.
- b. All persons associated with the VA Research Program have an obligation to cooperate in good faith with research misconduct proceedings.
- c. For any research staff facing an allegation of potential research misconduct, timely, written notification of the allegations, with reasonable access to data or other evidence, will be provided.
- d. In all respects, research staff facing allegations of potential misconduct will be entitled to due process with regard to formal inquiries or investigations that may be required.
- e. Legal counsel, or a personal advisor, may be present during inquiries or investigative proceedings, but may not speak for, or on behalf of, the research staff member facing allegations. In all respects, the privacy of all participants and the confidentiality of information that may be gathered during a research misconduct proceeding will be protected to the maximum extent possible. All documents and evidence relevant to a research misconduct proceeding will be carefully secured and itemized in order to protect the integrity of the data gathering process.
- f. The general procedures of VA Handbook 0700 entitled "Administrative Investigations" will be followed in all respects, and the timelines specified in VHA Handbook 1058.2 will be followed. Adjudication of a research misconduct proceeding will involve review by the Research Integrity Officer, the Hospital Director, and the VISN Director.
- g. Following adjudication by the VISN Director, final review will occur at the level of the Office of Research Oversight (ORO) Central Office.
- h. Corrective actions will be proposed and implemented as appropriate to the circumstances surrounding misconduct.
- i. An appeal mechanism will be available to research staff facing rulings of research misconduct; the filing period for appeals will be within 30 days of receiving a notice of a finding of research misconduct.
- j. As required by VHA Handbook 1058.1 entitled "Reporting Adverse Events in Research to the Office of Research Oversight," all allegations of potential research misconduct, results of research misconduct proceedings, and plans for corrective actions will be reported to ORO within the required timeframes.

7. **REFERENCES:**

- a. VHA Handbook 1200.5, Requirement for the Protection of Human Subjects in Research, Department of Veterans Affairs, Veterans Health Administration, Washington, DC
- b. VHA Handbook 1058.1, *Reporting Adverse Events in Research to the Office of Research Oversight*, Department of Veterans Affairs, Veterans Health Administration, Washington, DC
- c. VHA Handbook 1058.2, *Research Misconduct*, Department of Veterans Affairs, Veterans Health Administration, Washington, DC
- d. VA Handbook 0700, *Administrative Investigations*, Department of Veterans Affairs, Washington, DC
 - e. Federal Policy on Research Misconduct. 65 Fed. Reg. 76260 (December 6, 2000)
- 8. **FOLLOW-UP RESPONSIBILITY:** The ACOS/R&D is responsible for the follow-up of this HPM.
- 9. **RECISSIONS:** None.

APPROVED:

GARY L. CAMPBELL Director